

This policy applies to the following:

	Standard Opt-in	✓	PDPD	✓	VF		Medical Benefit
	Standard Opt-out	✓	ACSF		MMT		Medical Benefit: Managed Medicaid
		✓	Balanced		Marketplace		Medicare Part B

<b>Reference #</b>
3246-D

## EXCEPTIONS CRITERIA

### DISEASE-MODIFYING ANTIRHEUMATIC DRUGS FOR AUTOIMMUNE CONDITIONS

**PREFERRED PRODUCTS FOR ANKYLOSING SPONDYLITIS: COSENTYX, ENBREL AND HUMIRA**

**PREFERRED PRODUCTS FOR CROHN'S DISEASE: PRIMARY: HUMIRA; SECONDARY: STELARA SQ**

**PREFERRED PRODUCTS FOR PSORIASIS: HUMIRA, OTEZLA, SKYRIZI, STELARA, TALTZ, AND TREMFYA**

**PREFERRED PRODUCTS FOR PSORIATIC ARTHRITIS: COSENTYX, ENBREL, HUMIRA AND OTEZLA**

**PREFERRED PRODUCTS FOR RHEUMATOID ARTHRITIS: PRIMARY: ENBREL, HUMIRA, ORENCIA (SC)/ORENCIA CLICKJECT, RINVOQ, AND XELJANZ/XELJANZ XR; SECONDARY: KEVZARA**

**PREFERRED PRODUCTS FOR ULCERATIVE COLITIS: PRIMARY: HUMIRA; SECONDARY: XELJANZ/XELJANZ XR**

### POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

### I. PLAN DESIGN SUMMARY

This program applies to the disease-modifying antirheumatic drug (DMARD) products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. For psoriasis, this program applies to all adult members requesting treatment with a targeted product. For all other indications, this program applies to adult members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

**Table. Disease-modifying antirheumatic drugs for autoimmune conditions**

Indication	Primary Preferred Product	Secondary Preferred Product	Targeted Product(s)
Plaque psoriasis	<ul style="list-style-type: none"> <li>Humira (adalimumab)</li> <li>Otezla (apremilast)</li> </ul>	<ul style="list-style-type: none"> <li>None</li> </ul>	<ul style="list-style-type: none"> <li>Avsola (infliximab-axxq)</li> <li>Cimzia (certolizumab pegol)</li> <li>Cosentyx (secukinumab)</li> </ul>

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	<ul style="list-style-type: none"> <li>• <b>Skyrizi</b> (risankizumab-rzaa)</li> <li>• <b>Stelara</b> (ustekinumab)</li> <li>• <b>Taltz</b> (ixekizumab)</li> <li>• <b>Tremfya</b> (guselkumab)</li> </ul>		<ul style="list-style-type: none"> <li>• <b>Enbrel</b> (etanercept)</li> <li>• <b>Ilumya</b> (tildrakizumab-asmn)</li> <li>• <b>Inflectra</b> (infliximab-dyyb)</li> <li>• <b>Renflexis</b> (infliximab-abda)</li> <li>• <b>Siliq</b> (brodalumab)</li> </ul>
<b>Ankylosing spondylitis</b>	<ul style="list-style-type: none"> <li>• <b>Cosentyx</b> (secukinumab)</li> <li>• <b>Enbrel</b> (etanercept)</li> <li>• <b>Humira</b> (adalimumab)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>None</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Avsola</b> (infliximab-axxq)</li> <li>• <b>Cimzia</b> (certolizumab pegol)</li> <li>• <b>Inflectra</b> (infliximab-dyyb)</li> <li>• <b>Renflexis</b> (infliximab-abda)</li> <li>• <b>Simponi</b> (golimumab)</li> <li>• <b>Taltz</b> (ixekizumab)</li> </ul>
<b>Psoriatic arthritis</b>	<ul style="list-style-type: none"> <li>• <b>Cosentyx</b> (secukinumab)</li> <li>• <b>Enbrel</b> (etanercept)</li> <li>• <b>Humira</b> (adalimumab)</li> <li>• <b>Otezla</b> (apremilast)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>None</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Avsola</b> (infliximab-axxq)</li> <li>• <b>Cimzia</b> (certolizumab pegol)</li> <li>• <b>Inflectra</b> (infliximab-dyyb)</li> <li>• <b>Orencia</b> (abatacept)</li> <li>• <b>Renflexis</b> (infliximab-abda)</li> <li>• <b>Simponi</b> (golimumab)</li> <li>• <b>Stelara</b> (ustekinumab)</li> <li>• <b>Taltz</b> (ixekizumab)</li> <li>• <b>Xeljanz/Xeljanz XR</b> (tofacitinib)</li> </ul>
<b>Rheumatoid arthritis</b>	<ul style="list-style-type: none"> <li>• <b>Enbrel</b> (etanercept)</li> <li>• <b>Humira</b> (adalimumab)</li> <li>• <b>Orencia (SC)/Orencia Clickject</b> (abatacept)</li> <li>• <b>Rinvoq</b> (upadacitinib)</li> <li>• <b>Xeljanz/Xeljanz XR</b> (tofacitinib)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Kevzara (after 2 primary preferred products)</b> (sarilumab)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Actemra</b> (tocilizumab)</li> <li>• <b>Avsola</b> (infliximab-axxq)</li> <li>• <b>Cimzia</b> (certolizumab pegol)</li> <li>• <b>Inflectra</b> (infliximab-dyyb)</li> <li>• <b>Kineret</b> (anakinra)</li> <li>• <b>Olumiant</b> (baricitinib)</li> <li>• <b>Orencia IV</b> (abatacept)</li> <li>• <b>Renflexis</b> (infliximab-abda)</li> <li>• <b>Simponi</b> (golimumab)</li> </ul>
<b>Crohn's disease</b>	<ul style="list-style-type: none"> <li>• <b>Humira</b> (adalimumab)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Stelara SQ</b> (ustekinumab)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Avsola</b> (infliximab-axxq)</li> <li>• <b>Cimzia</b> (certolizumab pegol)</li> <li>• <b>Entyvio</b> (vedolizumab)</li> <li>• <b>Inflectra</b> (infliximab-dyyb)</li> <li>• <b>Renflexis</b> (infliximab-abda)</li> <li>• <b>Stelara IV</b> (ustekinumab)</li> </ul>
<b>Ulcerative colitis</b>	<ul style="list-style-type: none"> <li>• <b>Humira</b> (adalimumab)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Xeljanz/Xeljanz XR</b> (tofacitinib)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Avsola</b> (infliximab-axxq)</li> <li>• <b>Entyvio</b> (vedolizumab)</li> <li>• <b>Inflectra</b> (infliximab-dyyb)</li> <li>• <b>Renflexis</b> (infliximab-abda)</li> <li>• <b>Simponi</b> (golimumab)</li> <li>• <b>Stelara</b> (ustekinumab)</li> </ul>

Abbreviations: IV = intravenous; SQ = subcutaneous

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## II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

- A. Ankylosing spondylitis
  1. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Cosentyx, Enbrel, and Humira), unless there is a documented clinical reason to avoid a TNF-inhibitor (see Appendix)
  2. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs
  3. The requested product is Cimzia and member is currently pregnant or breastfeeding
- B. Crohn's disease
  1. Member has a documented inadequate response or intolerable adverse event with the primary preferred product (Humira) and with the secondary preferred product (Stelara SQ), unless there is a documented clinical reason to avoid Humira (see Appendix)
  2. The requested product is Stelara and member has a documented inadequate response or intolerable adverse event with the primary preferred product (Humira), unless there is a documented clinical reason to avoid Humira (see Appendix)
  3. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs
  4. The requested product is Cimzia and member is currently pregnant or breastfeeding.
- C. Psoriatic arthritis
  1. Member has a documented inadequate response or intolerable adverse event with at least three of the preferred products (Cosentyx, Enbrel, Humira, and Otezla), unless there is a documented clinical reason to avoid Enbrel and Humira (see Appendix)
  2. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs
  3. The requested product is Cimzia and member is currently pregnant or breastfeeding
- D. Plaque psoriasis
  1. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Humira, Otezla, Skyrizi, Stelara, Taltz, Tremfya); unless there is a documented clinical reason to avoid Humira (see Appendix)
  2. The requested product is Cimzia and member is currently pregnant or breastfeeding
- E. Rheumatoid arthritis
  1. The requested product is Kevzara and member has a documented inadequate response or intolerable adverse event with at least two of the preferred products (Enbrel, Humira, Orencia SQ/Clickject, Rinvoq, Xeljanz/Xeljanz XR).
  2. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Enbrel, Humira, Kevzara, Orencia (subcutaneous)/Orencia ClickJect, Rinvoq, and Xeljanz/Xeljanz XR); unless there is a documented clinical reason to avoid Enbrel and Humira (see Appendix).

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3. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs
  4. The requested product is Cimzia and member is currently pregnant or breastfeeding.
- F. Ulcerative colitis
1. Member has had a documented inadequate response or intolerable adverse event with Humira and with the secondary preferred product (Xeljanz/Xeljanz XR) unless there is a documented clinical reason to avoid Humira (see Appendix).
  2. The requested product is Xeljanz/Xeljanz XR and member has a documented inadequate response or intolerable adverse event with the primary preferred product (Humira), unless there is a documented clinical reason to avoid Humira (see Appendix)
  3. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs

### III. Appendix: Clinical reasons to avoid a preferred TNF inhibitor(s)

- History of demyelinating disorder
- History of congestive heart failure
- History of hepatitis B virus infection
- Autoantibody formation/lupus-like syndrome
- Risk of lymphoma

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